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U.S. FOOD & DRUG ADMINISTRATION

Selection of Strain(s) to be Included in the Periodic Updated COVID-19 Vaccines for the 2023-2024 Vaccination Campaign

Vaccines and Related Biological Products Advisory Committee Meeting

David C. Kaslow, M.D.
Director, Office of Vaccines Research and Review/CBER/FDA
June 15, 2023

Since 26 JAN 2023 VRBPAC

- Consolidation of Emergency Use Authorization for mRNA COVID-19 vaccines
  - Initial simplification of immunization schedule
  - Harmonization of Strain Composition from Monovalent (Original) to Bivalent (Original and Omicron BA.4/BA.5)
- FDA/BARDA- Joint Workshop on Recombinant Protein-based COVID-19 Vaccines

Simplified Approach for Periodic Vaccination Campaigns
An Age- and Risk-Based Immunization Schedule

General Population (age-based; single dose)*	Risk-based adjustments (dose(s) and schedule to be determined) **
Most adults, adolescents, and older children **Young children** *previously vaccinated with a COVID-19 vaccine*	**Older adults** **Persons with compromised immunity** **Young children** *not previously vaccinated with a COVID-19 vaccine*

*Presumed to have had sufficient S protein exposures such that a single dose of a COVID-19 vaccine induces or restores vaccine effectiveness

**Presumed to have insufficient preexisting immunity based on age and other risks (e.g., young children not previously vaccinated, older adults with higher-level risk for severe COVID-19 and death, and persons with compromised immunity); may require more than one dose of vaccine in each COVID-19 vaccination campaign; doses and schedule to be determined.

Recombinant Protein-Based COVID-19 Vaccines Workshop

APRIL 27, 2023

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FDA/BARDA- Joint Workshop

"Overcoming challenges to address strain updates and pandemic readiness"

Case Study: Strain Updates of Recombinant Protein-based COVID-19 Vaccines

- **Objective:**
  - Discuss timely availability of additional updated COVID-19 vaccines, beyond current nucleic acid-based vaccines, approved for use at the onset of periodic vaccination campaigns.
- **Recombinant Protein-based Platforms Reviewed:**
  - Bacteria
  - Baculovirus
  - Chinese Hamster Ovary (CHO)
  - Fungi
  - Yeast
- **Round Table Discussion:**
  - Achieving the timeline from an updated strain recommendation to the launch* of approved periodic updated recombinant protein-based COVID-19 vaccines simultaneous with the launch of approved periodic updated mRNA COVID-19 vaccines

*inclusive of remaining development and evaluation of updated vaccine candidate(s) after strain recommendation, manufacture scale-up and release of periodic updated vaccine, and regulatory and recommendation for use reviews

Meeting Objective

VRBPAC to discuss and make recommendations on the selection of strain(s) to be included in periodic updated COVID-19 vaccines for the 2023–2024 vaccination campaign

Key considerations:

- Need for a periodic update (i.e., strain change)
- Change from current bivalent to monovalent composition
- Selection of strain(s) (e.g., XBB-lineage)

Approach to *Periodic Updates* of Current COVID-19 Vaccines

(from 26 JAN 2023 VRBPAC)

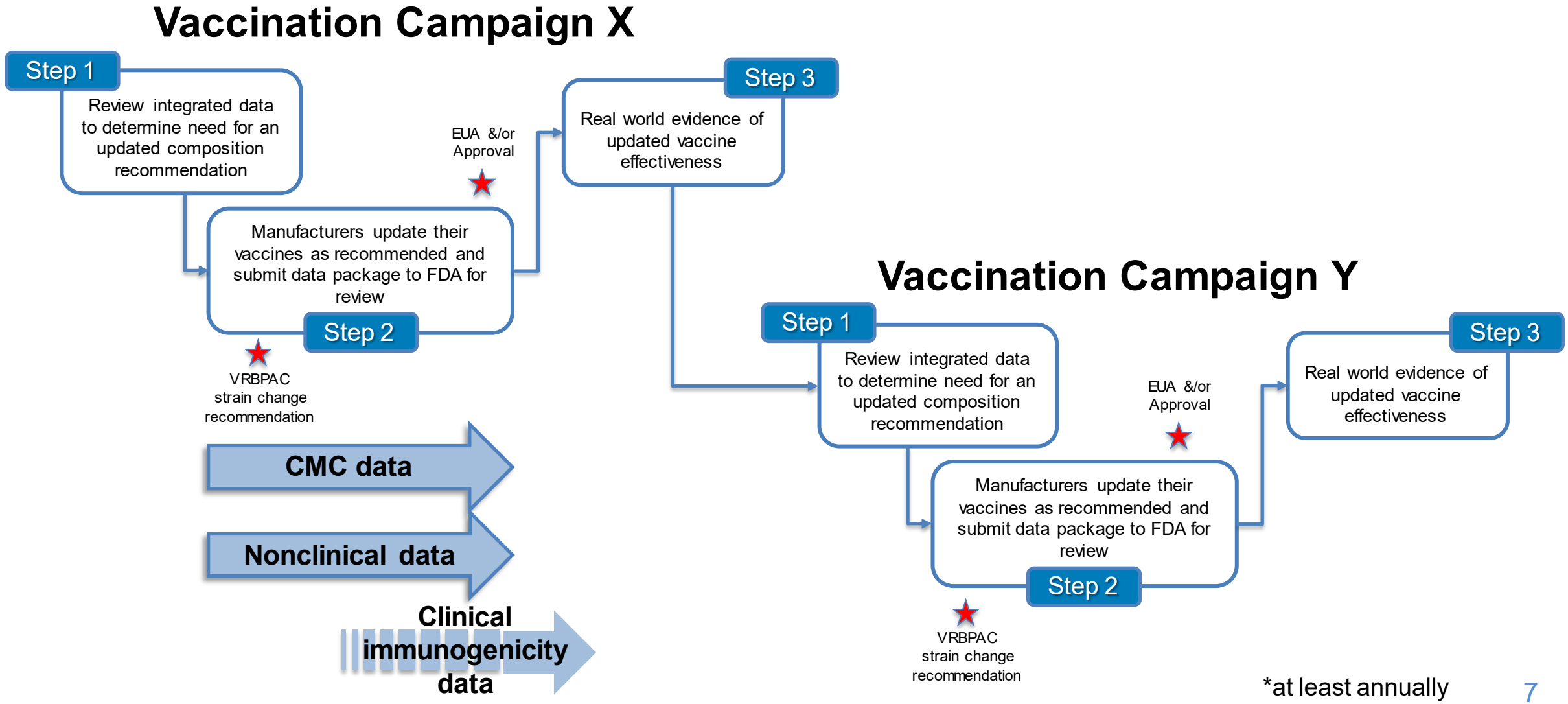
Current state

Continued rapid evolution of SARS-CoV-2 and waning of vaccine-induced immunity will likely require revaccination with periodically updated S protein sequence(s) contained or encoded in current COVID-19 vaccines

Desired future state

An evidence-driven approach, similar in many ways to the process used for influenza vaccines, to monitor and update, as needed, the composition used in all COVID-19 vaccines to induce or restore protective immunity through periodic vaccination campaigns

Approach to updating vaccine composition: High-level overview of a continuous* iterative 3-step process



*at least annually

Overview of Today's Agenda

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
182nd Meeting of the Vaccines and Related Biological Products Advisory Committee
June 15, 2023
AGENDA

EST Time	Presentation/Presenter
8:30 a.m.	**Opening Remarks: Call to Order and Welcome (5 Min)** • Arnold Monto, M.D. Acting Chair, VRBPAC Emeritus Professor of Public Health and Epidemiology University of Michigan **Administrative Announcements, Roll Call, Introduction of Committee, Conflict of Interest Statement (15 Min)** • Sussan Paydar, Ph.D. Designated Federal Officer, VRBPAC Division Of Scientific Advisors and Consultants Center for Biologics Evaluation and Research (CBER), FDA
8:50 a.m.	**FDA Introduction (20 Min)** **Opening Remarks (5 Min)** • Peter Marks, M.D. Ph.D. Center Director, CBER, FDA **Considerations for Selection of the composition of COVID-19 Vaccines for the 2023-2024 Season (10 Min)** • David C. Kaslow, M.D. Director Office of Vaccines Research and Review (OVRR), CBER, FDA Q/A – 5 Min
9:10 a.m.	**CDC Presentations (60 Min total including Q/A)** **Update on COVID-19 Vaccine Bivalent Effectiveness (25 Min)** • Ruth Link-Gelles, PH.D., M.PH. LCDR, U.S. Public Health Service COVID-19 Vaccine Effectiveness Program Lead National Center for Immunization and Respiratory Diseases, CDC
	Q/A – 5 Min **Update on Current Epidemiology of the COVID-19 Pandemic and SARS-CoV-2 Variants (25 Min)** • Natalie J. Thornburg, Ph.D. Acting Chief, Laboratory Branch Coronavirus and Other Respiratory Viruses Division National Center for Immunization and Respiratory Diseases, CDC Q/A – 5 Min
10:10 a.m.	**WHO Presentation (35 Min Total including Q/A)** **WHO TAG-CO-VAC May 2023 recommendation on the antigen composition of COVID-19 vaccines (25 minutes)** • Kanta Subbarao, M.D. M.PH. Director, WHO Collaborating Center for Research and Reference on Influenza, The Peter Doherty Institute for Infection and Immunity, Melbourne, Australia Q/A – 10 Min
10:45 a.m.	**Break (15 min)**
11:00 a.m.	**Moderna Presentation (30 Min Total including Q/A)** **Moderna COVID-19 Variant Vaccines (25 minutes)** • Rituparna Das - VP, Clinical Development – Therapeutic Area Head, Respiratory Vaccines • Darin Edwards – Executive Director, COVID-19 Lead Q/A –5 Min

Overview of Today's Agenda Continued

11:30 a.m.	**Pfizer presentation (30 Min Total including Q/A)** **2023-24 COVID-19 Vaccine Formula: Pfizer/BioNTech Clinical and Preclinical Supportive Data (25 minutes)** • Kena A. Swanson, Ph.D. Vice President, Viral Vaccines, Vaccine Research and Development, Pfizer Inc. Q/A –5 Min
12:00 p.m.	**Novavax presentation (30 Min Total including Q/A)** **Novavax Data in Support of 2023-2024 Vaccine Update (25 Min)** • Filip Dubovsky, M.D. Executive Vice President and Novavax Chief Medical Officer Novavax Q/A – 5 min
12:30 p.m.	**Lunch (30 Min)**
1:00 p.m.	**Open Public Hearing (60 Min)**
2:00 p.m.	**FDA Presentation (30 Min Total including Q/A)** **FDA Considerations and Recommendation for Changes to COVID-19 Vaccine Strain Composition (25 Min)** • Jerry Weir, Ph.D. Director, Division of Viral Products Office of Vaccines Research and Review, CBER, FDA Q/A - 5 Min
2:30 p.m.	**Additional Q & A for CDC, FDA and Sponsor Presenters (20 Min)**
2:50 p.m.	**Break (10 min)**

3:00 p.m.	**Committee Discussion of Vaccine Strain Selection and Voting (120 Min)**
5:00 p.m.	**Meeting Adjourned - DFO**

Voting Question for VRBPAC

1. For the 2023-2024 Formula of COVID-19 vaccines in the U.S., does the committee recommend a periodic update of the current vaccine composition to a monovalent XBB-lineage?

Please vote "Yes" or "No" or "Abstain"

Discussion Topic

Based on the evidence and other considerations presented, please discuss selection of a specific XBB lineage (e.g., XBB.1.5 or XBB.1.16 or XBB.2.3) for inclusion in the 2023-2024 Formula of COVID-19 vaccines in the U.S.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